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EXAMINER
BAUM, STUART F

ART UNIT	PAPER NUMBER
1638	8

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/936,612	Applicant(s) XIE ET AL.	
	Examiner Stuart F. Baum	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *4/21/03*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-42* is/are pending in the application.

4a) Of the above claim(s) *1-13,25-27 and 37-42* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-24 and 28-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 1/2/02 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Claims 1-42 are pending.

2. Applicant's election of Group III, claims 14-24 and 28-36, in Paper No. 7 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-13, 25-27 and 37-42 are withdrawn from consideration for being drawn to non-elected inventions.

3. Claims 14-24 and 28-36 are examined in the present office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 14-24 and 28-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Dependent claims are also rejected.

In claim 14, the recitations "activating" and "activated" are undefined. It is unclear what is meant by "activating *Agrobacterium tumefaciens*". All subsequent recitations of "activating" and "activated" are also rejected.

In claim 14, the metes and bounds of "preculturing" have not been defined. It is unclear what is encompassed by a "preculturing" step and what is not considered part of a "preculturing" step. All subsequent recitations of "preculturing" are also rejected.

In claim 32, the recitation "AM-265" is not defined. On page 9, Applicant describes components of different media but it is unclear what the abbreviations mean. For example, the abbreviation "TDZ" is not defined.

In claim 33, the metes and bounds of a "mannitol solution" have not been defined. Applicant has not specified the concentration of the solution; what constitutes a "mannitol solution"?

In claim 34, the recitation "induction medium" has not been defined. It is unclear what constitutes an "induction medium".

Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 14-24 and 28-36 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to a method of transforming *Acacia mangium* with a gene of interest comprising somehow "activating" *Agrobacterium*, preculturing any explant (including roots, pollen, or embryos) of *Acacia mangium*, co-cultivating said *Agrobacterium* with said explant, culturing the *Agrobacterium* infected explant to induce callus and adventitious buds, and

culturing said callus or adventitious buds on a selective medium. The claims are also drawn to a method of preparing transgenic *Acacia mangium* cells comprising preculturing stem pieces of *Acacia mangium* in a culture medium and cocultivating said stem pieces with activated *Agrobacterium*. Given the 112 2nd paragraph issues discussed above and the broad interpretation of terms such as "preculturing an explant", "co-cultivating", and "culturing said callus or adventitious buds on a selective medium" for example, the Office interprets these terms and phrases to mean any non-specific treatment of any tissue to yield a transformed, regenerated plant.

In contrast, the specification only provides guidance for obtaining a transformed *Acacia mangium* plant by preculturing bud, leaflet, petiole or stem explants from adventitious shoots, in a mannitol solution on a particular culture medium, preculturing *Agrobacterium* on a particular activation medium, utilizing acetosyringone to induce *Agrobacterium*-mediated transformation, culturing transformed stem explants on particular media to induce callus and adventitious buds, and further subculturing the transformed adventitious buds to form shoots and whole plants.

Applicant's broadly claimed invention reads on a multitude of conditions which would lead to unpredictable results as evidenced by Applicant's own admission of the recalcitrance of *A. magnum* to tissue culture or transformation, in which Applicants state "There has been no report on regeneration or genetic transformation of *A. mangium*" (page 3, 2nd paragraph).

The state-of-the-art teaches that specific conditions and chemical components are required to achieve a successful transformation of a plant. Hansen et al (1999, Trends in Plant Science 4(6):226-231) teach that successful transformation of plants demands that certain criteria be met (page 227, under "Transformation systems"). Some of the requirements are that target

tissues are competent for propagation or regeneration, an efficient DNA delivery method, and the ability to recover fertile transgenic plants at a reasonable frequency. Hansen et al also teach that there are variables that need to be tested to ensure success. These variables include the use of feeder cells, alternative *Agrobacterium* strains, infiltration of the bacteria, and the duration and temperature of co-cultivation (page 228, right column, 3rd paragraph). Hansen also teaches that some crops appear to react or be hypersensitive to *Agrobacerium* and form necrotic barriers. To overcome this reaction, the addition of antioxidants is required (page 228, right column, last paragraph).

Given the claim breadth, teachings of the state-of-the-art and unpredictability as stated above; given the specific conditions that are required to achieve a successful transformation of *Acacia mangium* that are taught by way of example and disclosure; given the breadth of the claims which encompass a plethora of tissue culture conditions not exemplified by Applicant; it would require undue experimentation by one skilled in the art to identify a transformation and regeneration protocol that is suitable for the transformation of *Acacia mangium* from the plethora of exemplified and non-exemplified protocols from the multitude of plant transformation and regeneration protocols in the art.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 14, 18, 20-22, 28-31, and 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al (July, 1997, WO 97/23126) in view of Bhaskar et al (1996, Indian Journal of Experimental Biology 34:590-591).

The claims are drawn to a method of transforming *Acacia mangium* with a gene of interest comprising activating *Agrobacterium*, preculturing an explant of *Acacia mangium*, co-cultivating said *Agrobacterium* with said explant, culturing the *Agrobacterium* infected explant to induce callus and adventitious buds, and culturing said callus or adventitious buds on a selective medium, wherein the co-cultivating step is performed in the dark, and the preculture and culturing on selective medium steps are performed using a photoperiod of 16 hours light/8 hours dark and the explant is a selected from the group consisting of stem, leaflet, petiole and bud. The claims are also drawn to a method of preparing transgenic *Acacia mangium* cells comprising preculturing stem pieces of *Acacia mangium* in a culture medium and cocultivating said stem pieces with activated *Agrobacterium*, wherein the preculturing is performed for 3 days using 1800-2000 lux for the light cycles, at 28^0C and wherein the *Agrobacterium* were prepared by growing them in induction medium, in the dark at 28^0C. Given the 112 2nd paragraph issues discussed above and the broad interpretation of terms such as "preculturing an explant", "co-cultivating", and "culturing said callus or adventitious buds on a selective medium" for example, the Office interprets these terms and phrases to mean any non-specific treatment of any tissue to yield a transformed, regenerated plant. Given the 112 2nd indefiniteness for "induction medium", the Office interprets this term to read on any medium.

Edwards et al teach a method for transformation of a Eucalyptus tree species comprising preparing a culture of *Agrobacterium* at 28^0C to be used for transformation of plant material; the preparation of Eucalyptus explants for transformation, wherein the explants are leaf, petiole or stem explants; co-cultivation of explants with *Agrobacterium* in the dark; selection, multiplication and regeneration of transgenic tissue using 16 hours light/8 hours dark (pages 65-76).

Edwards et al do not teach specifically transforming *Acacia mangium* plants or cells as recited above.

Bhaskar et al teach a method for regenerating whole *Acacia mangium* plants from adventitious buds (see page 590, Abstract).

Given the recognition of those of ordinary skill in the art of the value of transforming a tree for genetic improvement as taught by Edwards et al, and given the importance of *Acacia mangium* as a fast growing and nitrogen fixing thornless exotic tree legume, used for reforestation and soil rehabilitation, wherein tissue culture techniques facilitate genetic improvement thereof, as taught by Bhaskar et al (page 590, column 1, middle paragraph), it would have been obvious to optimize the method of Edwards et al so as to transform and regenerate *Acacia mangium* using optimization of process parameters. The methods of Edwards et al, i.e., the culture conditions for *Agrobacterium*, the co-cultivation steps, the light conditions and temperature of the selection and growth conditions, are all very standard conditions and would ensure a reasonable expectation for success using *Acacia mangium.*

Thus the claimed invention would have been *prima facie* obvious as a whole to one of ordinary skill in the art at the time it was made, especially in the absence of evidence to the contrary.

7. Claims 14, 18, 20-24, 28-31, and 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al (July, 1997, WO 97/23126) in view of Bhaskar et al (1996, Indian Journal of Experimental Biology 34:590-591) further in view of Mohamed et al (1996, Plant Cell Tissue and Organ Culture 46:161-164).

The claims are drawn to a method of transforming *Acacia mangium* with a gene of interest comprising activating *Agrobacterium*, preculturing an explant of *Acacia mangium*, co-cultivating said *Agrobacterium* with said explant, culturing the *Agrobacterium* infected explant to induce callus and adventitious buds, and culturing said callus or adventitious buds on a selective medium, wherein the co-cultivating step is performed in the dark, and the preculture and culturing on selective medium steps are performed using a photoperiod of 16 hours light/8 hours dark and the explant is a selected from the group consisting of stem, leaflet, petiole and bud. The method also includes growing the transformed buds on medium comprising gibberellic acid to promote elongation of transformed adventitious buds and for promoting pinnate leaf formation. The claims are also drawn to a method of preparing transgenic *Acacia mangium* cells comprising preculturing stem pieces of *Acacia mangium* in a culture medium and cocultivating said stem pieces with activated *Agrobacterium*, wherein the preculturing is performed for 3 days using 1800-2000 lux for the light cycles, at 28^0C and wherein the *Agrobacterium* were prepared by growing them in induction medium, in the dark at 28^0C. Given the 112 2nd paragraph issues

discussed above and the broad interpretation of terms such as "preculturing an explant", "co-cultivating", and "culturing said callus or adventitious buds on a selective medium" for example, the Office interprets these terms and phrases to mean any non-specific treatment of any tissue to yield a transformed, regenerated plant.

The teachings of Edwards et al in view of Bhaskar et al have been discussed above.

Edwards et al in view of Bhaskar et al do not teach adding gibberellic acid the culture medium to promote elongation of transformed adventitious buds or to promote pinnate leaf formation on transformed adventitious buds of *Acacia mangium*.

Mohamed et al teach the use of gibberellic acid to promote leaf bud formation and expansion (page 163, Table 1).

Given the recognition of those of ordinary skill in the art of the value of transforming *Acacia mangium* for genetic improvement as taught by Edwards et al in view of Bhaskar et al, one of ordinary skill in the art would have been motivated to transform *Acacia mangium* according to the method of Edwards et al in view of Bhaskar et al, and to optimize it via the method of Mohamed et al for the purpose of producing many elongated pinnate leaves originating from transformed buds with a reasonable expectation of success.

Thus the claimed invention would have been *prima facie* obvious as a whole to one of ordinary skill in the art at the time it was made, especially in the absence of evidence to the contrary.

8. Claims 15-17, 19 and 32-33 are deemed free of the prior art given the failure of the prior art to teach or reasonably suggest the claimed media supplements and their use to transform and regenerate *Acacia mangium*.

9. No claims are allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart Baum whose telephone number is (703) 305-6997. The examiner can normally be reached on Monday-Friday 8:30AM – 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 or (703) 305-3014 for regular communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist, who may be contacted at 308-0196.

Stuart F. Baum Ph.D.

June 27, 2003

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180 1638